IN THE SPECIFICATION

[0004] Typically, the balloon is placed within the body of the subject by threading a carrier catheter having the balloon attached thereto into the body of the subject through the vascular system or other passages within the body and into the desired treatment location with the balloon in a deflated condition. Once the balloon is at the desired location within the subject's body, the balloon is inflated, the desired procedure is performed and the balloon is again deflated and withdrawn by withdrawing the carrier catheter. In many procedures, it is desirable to maintain alignment between portions of the balloon, and to maintain alignment between features of the balloon and the carrier catheter while the balloon is in an inflated condition. For example, in certain preferred embodiments taught in the aforementioned '227 application, the ultrasonic transducer is mounted on a portion of the carrier catheter disposed within the balloon adjacent a proximal end of the balloon. The ultrasonic transducer is generally cylindrical and is coaxial with the carrier catheter. When the balloon is in an inflated condition, the proximal to distal, or lengthwise, axis of the balloon should also be coaxial with the transducer for optimum focusing of the ultrasonic energy.

[0023] A flexible, distensible tube 38 having an interior bore 40 extends between stop 30 and nosepiece 34. The proximal end of the tube is fastened to the stop 30 and, hence, to extension 26, carrier catheter 10 and the proximal end 12 of the balloon, whereas the distal end of the tube is fastened to the nosepiece. The interior bore 40 of tube 38 communicates with the bore 36 in the nosepiece and with the bore 28 within extension 26, so that the extension 26, tube 40 and nosepiece 36

cooperatively define a continuous passage communicating with the central bore 14 of the carrier catheter and extending through the interior of balloon 16, this passable opening to the exterior of the main balloon 16 at the distal end 20 of the main balloon. Tube 38 desirably is formed from a material such as an expanded polymer as, for example, expanded polytetraflourethylene ("PTFE") or expanded polyethylene. Where the expanded polymer itself is porous, the tube may have a very thin covering of ~~an~~ a deformable, nonporous material such as an elastomer. Expanded PTFE tubes sold by Impra, Inc., a subsidiary of C. R. Bard, Inc., of Tempe, Arizona, USA, and commonly employed as a vascular graft material may be employed. Tubes formed from the preferred materials have the property that the interior bore of the tube does not substantially contract in radial directions, transverse to the lengthwise direction along the axis of the tube, when the tube is stretched in the lengthwise direction. Although the present invention is not limited by any theory of operation, it is believed that this property results from the low Poisson's ratio of the material constituting the tube wall. Desirably, when the tube is stretched to the elongated state depicted in FIG. 1, with the balloon fully deflated, the interior diameter of the tube does not vary by more than about 20 percent of the nominal interior diameter, *i.e.*, the diameter of the tube in an axially-shortened, fully inflated condition as depicted in FIG. 2. Most typically, the tube and the interior bore are circular in cross-section. Thus, the diameter of the interior bore is simply the dimension of the interior bore in any direction transverse to the axial direction of the tube. If the tube has a non-circular cross-section, the diameter of the interior bore can be considered as the largest dimension in any direction transverse to the axial direction. Typically, the interior bore has a nominal diameter of about 0.8-1.2 mm and does not vary by more

than about 0.2 mm as the tube is stretched throughout the normal operating range, from the fully inflated condition to the fully deflated condition. Further, tubes formed from the preferred expanded polymer materials tend to resist collapse when subjected to external pressure. The most preferred materials, such as expanded PTFE, also have a low coefficient of friction which further facilitates passage of guidewires and other elements through the tube. Moreover, as further discussed below, the tube is stretched by the action of a coil spring during operation of the device. The preferred materials offer very low resistance to stretching.

[0034] The number of engagement elements can be varied. Apparatus according to a further embodiment of the invention (FIG. 3) is similar to the apparatus discussed above with reference to FIGS. 1 and 2 except that the two mobile engagement elements discussed above are replaced by a single mobile engagement element 144 which is fixed to the nosepiece 134 and hence to the distal end of the balloon. This mobile engagement element is a tubular structure similar to the mobile engagement elements discussed above, and surrounds the spring 142 and tube 138. In the deflated condition shown in FIG. 3, the proximal end of mobile engagement element 144 is remote from the fixed engagement element or stop 130. Thus, the assembly is free to flex in directions transverse to axis 124 in the gap 102 between the engagement elements. This flexibility facilitates threading of the assembly through the vascular system and removal of the assembly after treatment, in a manner similar to that discussed above. In the inflated condition, the proximal end of mobile engagement element 144 abuts the fixed engagement element or stop 130 to provide a column or support as discussed above. The assembly according to this embodiment, however, is more

resistant to kinking in the deflated condition, during threading and removal.

[0042] When the balloon 216 is in its deflated condition, the engagement elements 260, 270 are in the disengaged position illustrated in FIG. 4. The bulbous portion or ball joint surface 272 of the stem lies inside bore 266, adjacent the open proximal end of the bore. In this condition, the engagement elements 260 and 270 are pivotable relative to one another so that the axis 282 of the second engagement element can pivot relative to the axis 280 of the first engagement element through a predetermined angular range in any direction about the center of the spherical ball joint surface 272. As the second engagement element 260 pivots about the bulbous tip 272, the flexible material 238 and spring 266 can bend. The pivoting motion allows the balloon to flex in directions transverse to the catheter 210. This flexibility helps the catheter track over guide wires and maneuver through the anatomy during placement of the device in the patient and during removal from the patient. However, second engagement element 260 is substantially constrained by the stem, and particularly by the ball joint surface of bulbous portion 272, against translational movement relative to the first engagement element in directions transverse to the axis 280 of the first engagement element. This assures that the balloon 216, the tube 238 and spring 266 cannot kink. In the deflated condition, the proximal end of the second engagement element 260 may bear on the interior of balloon 216, particularly when the assembly is bent as shown in FIG. 4. However, the soft material 276 constituting the proximal end of the second engagement element 260 does not tend to cut or tear the balloon.

[0043] FIG. 5 shows the assembly with the balloon in its inflated state. As the balloon 216 inflates, the length of the balloon decreases and compresses the spring 262. As the spring 262 is compressed, the second engagement element 260 moves toward the first engagement element 270. ~~in~~ In this motion, the stem 274 moves deeper into bore 266 of the second engagement element. The progressive engagement of the stem in the bore will force the second engagement element into alignment with the first engagement element. This process continues as the proximal end of the first engagement element encounters the tapered guide surface 278 and then the first engagement element 270. In the fully inflated condition of FIG. 5, with the second engagement element 260 telescopically encompassing the first engagement element 270, the close fit between the exterior of the first engagement element and the interior of the second engagement element assures that the engagement elements are coaxial with one another, so that axis 282 is coincident with axis 280. The distal end of the balloon is held precisely coaxial with the proximal end of the balloon, and hence coaxial with the transducer 250 and with the reflective parabolic interface region defined by balloon 216 and auxiliary balloon 222. Upon deflation, spring 262 forces the second engagement element away from the first engagement element, and thus stretches the balloon 216 axially, restoring the assembly to the flexible condition depicted in FIG. 4. The engagement elements disengage one another up to the point of where the second engagement element 260 still encompasses the bulbous tip 272 of stem 274. In this embodiment, the spring may or may not twist the balloon during deflation to assist in orderly collapse of the balloon as discussed above.

[0045] Apparatus according to another embodiment includes a third engagement element 350 (FIG. 6). The third engagement

element 350 is also referred to as a "female" engagement element as it is a hollow tube defining an axis 382 and a cylindrical interior bore 366. The third engagement element has a similar structure to that described above with reference to FIGS. 4 and 5 for the second engagement element 260, while the second middle engagement element 360 has a proximal end resembling that of the previously described second engagement element 260 and a distal end resembling that of the previously described first engagement element. Thus, a stem 374 projects from the distal end of the second or middle engagement element, such stem having a bulbous element 372. Here again, the engagement elements desirably are formed from substantially rigid materials, except that the second engagement element 360 and the third engagement element 350 each have a relatively soft material such as a polymer at their respective proximal ends to prevent damage to the balloon caused by engagement between the balloon and the proximal ends of these elements in the deflated condition. In the deflated condition illustrated, the engagement elements are free to pivot relative to one another about the bulbous tips of the stems in the same manner as discussed above with reference to FIGS. 4 and 5. In the inflated condition, the third engagement element 350 telescopically receives the exterior of the second engagement element 360 and the second engagement element telescopically receives the exterior of the first engagement element 370. Here again, the engaged elements are constrained in coaxial relationship with one another, thereby keeping the proximal and distal ends of the balloon in precise alignment with one another, and in precise alignment with internal structures such as a transducer 301, when the balloon is in the inflated condition.